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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/134,472	08/14/98	ROSS	D 227662XY4-S

HM12/0901

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EXAMINER	
OWENS JR, H	
ART UNIT	**PAPER NUMBER**
1623	6

DATE MAILED: 09/01/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/134,472	Ross et al.
Examiner	**Group Art Unit**
Howard Owens	1623

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-22* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-22* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CAR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claim Objections

Claim 1 appears to contain the misspelled term "adminstering".

Appropriate correction is required for these and any other spelling or grammatical errors not noted herein.

Specification

The content of the specification does not conform with to the preferred content of a patent application for prosecution in front of the United States Patent and Trademark Office. The following guidelines illustrate the preferred content for patent applications. These guidelines are suggested for the applicant's use.

Content of Specification

(a) Title of the Invention. (See 37 C.F.R. § 1.72(a)). The title of the invention should be placed at the top of the first page of the specification. It should be brief but technically accurate and descriptive, preferably from two to seven words.

(b) Cross-References to Related Applications: See 37 C.F.R. § 1.78 and section 201.11 of the M.P.E.P.

© Statement as to rights to inventions made under Federally sponsored research and development (if any): See section 310 of the M.P.E.P.

(d) Background of the Invention: The specification should set forth the Background of the Invention in two parts:

(1) Field of the Invention: A statement of the field of art to which the invention pertains. This statement may include a paraphrasing of the applicable U.S. patent classification definitions of the subject matter of the claimed invention. This item may also be titled "Technical Field".

(2) Description of the Related Art: A description of the related art known to the applicant and including, if applicable, references to specific related art and problems involved in the prior art which are solved by the applicant's invention. This item may also be titled "Background Art".

(e) Summary: A brief summary or general statement of the invention as set forth in 37 C.F.R. § 1.73. The summary is separate and distinct from the abstract and is directed toward the invention rather than the disclosure as a whole. The summary may point out the advantages of the invention or how it solves problems previously existent in the prior art (and preferably indicated in the Background of the Invention). In chemical cases it should point out in general terms the utility of the invention. If possible, the nature and gist of the invention or the inventive concept should be set forth. Objects of the invention should be treated briefly and only to the extent that they contribute to an understanding of the invention.

(f) Brief Description of the Drawing(s): A reference to and brief description of the drawing(s) as set forth in 37 C.F.R. § 1.74.

(g) Description of the Preferred Embodiment(s): A description of the preferred embodiment(s) of the invention as required in 37 C.F.R. § 1.71. The description should be as short and specific as is necessary to describe the invention adequately and accurately. This item may also be titled "Best Mode for Carrying Out the Invention". Where elements or groups of elements, compounds, and processes, which are conventional and generally widely known in the field of the invention described and their exact nature or type is not necessary for an understanding and use of the

invention by a person skilled in the art, they should not be described in detail. However, where particularly complicated subject matter is involved or where the elements, compounds, or processes may not be commonly or widely known in the field, the specification should refer to another patent or readily available publication which adequately describes the subject matter.

(h) Claim(s) (See 37 C.F.R. § 1.75): A claim may be typed with the various elements subdivided in paragraph form. There may be plural indentations to further segregate subcombinations or related steps.

(I) Abstract: A brief narrative of the disclosure as a whole in a single paragraph of 250 words or less.

Reference to Co-Pending Application

It is noted that this application appears to claim subject matter disclosed in prior copending application Serial No. 09/134,420 filed 8/14/98. A reference to the prior application must be inserted as the first sentence of the specification of this application if applicant intends to rely on the filing date of the prior application under 35 U.S.C. § 120. See 37 C.F.R. § 1.78(a). Also, the present status of all parent applications should be included.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CAR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground

provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CAR 1.130(b). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CAR 3.73(b).

Claims 12-22 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 5,935,989 ('989). Although the conflicting claims are not identical, they are not patentably distinct from each other because the pharmaceutical compositions of N-linked urea and carbamates of heterocyclic thioesters of Formula I of the instant claims have been set forth as pharmaceutical compositions in the claims cited supra of '989. The claims of the instant application differ only by the addition of further alkyl and aromatic groups, which constitute obvious substitutions in the Markush groups of the analogous compounds set forth in '989.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention.

The instant specification invites the skilled artisan to experiment. The factors which must be considered in determining undue experimentation are set forth in In re Wands 8USPQ 2d 1400. The factors include:

1) quantity of experimentation necessary,
2) the amount of guidance presented,
3) the presence or absence of working examples,
4) the nature of the invention,
5) the state of the prior art,
6) the predictability of the art,
7) breath of the claims and the
8) level of skill in the art.

Quantity of experimentation necessary, Amount of guidance presented, Presence or absence of working examples

Claims 1-11 are drawn to a method for treating a vision disorder, improving vision, treating memory impairment or enhancing memory performance in an animal, comprising administering to said animal an effective amount of an N-linked heterocyclic ring compound containing a carboxylic acid or carboxylic acid isostere moiety thereof attached to the 2-carbon of the N-heterocyclic ring.

There is not seen adequate representation in the instant specification to support the claims cited supra with regard to treating a vision disorder, improving vision, treating memory impairment or enhancing memory performance in an animal.

An inventor should be allowed to dominate future patentable inventions of others where those inventions were based in some way on his teachings, since such improvements, while unobvious

from his teachings, are still within his contribution, since improvement was made possible by his work; however, he must not be permitted to achieve this dominance by claims which are insufficiently supported and, hence, not in compliance with first paragraph of 35 U.S.C. 112; in cases involving unpredictable factors, such as most chemical reactions and physiological activity, scope of enablement varies inversely with degree of unpredictability of factors involved.

In the case of the instant specification, there is not seen adequate representation wherein the compounds of the invention are administered to diverse *in vivo* systems, i.e. human, birds, fish, reptiles, etc. and memory is enhanced or treatment of impairment is demonstrated in those with or without the various disorders correlated with sufficient data or guidance to memory and vision functions *in vivo*.

Applicant cites mice treated with the compounds of the invention and subjected to the Morris water maze used for assessing spatial memory formation and retention in experimental animals as an example of support for the claim to treating memory impairment or enhancing memory performance in an animal. Applicants sole animal model utilized mice and the improvements to memory were confined to that of spatial memory. However, there is not seen adequate representation wherein dosages for diverse animal species was given and disorders such as Alzheimer's, amnesia, Korsakoff's syndrome, etc. have been treated with the compounds of the invention and an improvement in the disorder was demonstrated.

Given that the visual systems vary between animal species as well as the multitude of vision disorders arising from various etiologies, a claim to the treatment of vision disorder or improving vision should be supported with adequate representation

commensurate to the breadth and scope of the claim(s). The examples cited by applicant to support the claims cited supra are not treatments, but rather suppositions that if the compounds of the invention are administered to various visual disorders such as uveitis, conjunctivitis, chronic exposure to ultraviolet light an improvement is expected. This is not seen as sufficient guidance or adequate representation(s) to support the treatment claims cited supra. Without the benefit of protocols for a diversity of animal systems such as dosages, routes of administration, one of skill in the art would be subject to undue experimentation in the practice of the invention.

State of the Art

The state of the art is such that no singular compound or class of compounds is known to exhibit activity for improving the broad spectrum of visual disorders and memory impairments. Wherein compounds such as phosphatidyl serine and choline have shown slight improvements in aiding short term memory and applicant's background of the field of this invention details various compounds which are effective for specific neurotrophic or vision disorders, but the art has not recognized the use of one agent which will broadly provide improvement in healthy states as well as impaired states for the host of visual disorders and memory impairments as instantly asserted. Where the art fails to provide guidance for making and using a singular class of compounds to support a broad spectrum of therapeutic efficacy, the specification submitted to provide enablement for such should necessarily provide such support to substantiate same.

Breadth of the claims

The instant claims are drawn to a method for treating a vision disorder, improving vision, treating memory impairment or enhancing memory performance in an animal, comprising administering to said animal an effective amount of an N-linked sulfonamide of a heterocyclic thioester compound. As drafted, the claimed compounds of the invention would seem to encompass treatment for a broad range of disorders for both vision and memory such as refractive disorders such as myopia and hyperopia; astigmatism; glaucoma; blindness- color or night; eye socket disorders such as orbital cellulitis, Cavernous Sinus Thrombosis,exophthalmos; disorders of the Conjunctiva; eyelid and tear gland disorders such as blepharitis; Corneal Disorders such as Superficial Punctate Keratitis, Corneal Ulcer, Keratomalacia; Cataracts, Retinal Disorders such as Macular Degeneration, Retinal Detachment, Retinitis Pigmentosa, Arteriosclerotic Retinopathy, Hypertensive Retinopathy, Retinal Artery Blockage, Retinal Vein Blockage and Diabetic Retinopathy; Optic Nerve Disorders such as Papilledema, Papillitis, Retrobulbar Neuritis and Toxic Amblyopia; Alzheimer's; Amnesia; Korsakoff's syndrome. One of skill in the art would recognize that there is no singular compound or class of compounds which would provide treatment or improvement for the broad spectrum of disorders cited supra. Moreover, applicants singular example is not seen to be demonstrative of art recognized test systems which would provide a correlation for the improvement of the broad spectrum of disorders cited supra.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-11 and 22 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is seen as vague and indefinite as applicant cites a method for improving vision, however applicant has not established a baseline or specific measure (be it unit of measure or otherwise) of what constitutes vision improvement. For instance, it is unclear as to whether applicant is improving color recognition, depth perception, or alleviating conditions such as myopia, astigmatism, etc. and to what degree of alleviation or improvement is intended. Accordingly, dependent claim 2-11 are rejected as they fail to obviate the rejections set forth in the parent claim.

In claim 22, it is unclear as to what applicant intends by setting forth the "group consisting of compounds 1-138", given that applicant has not set forth these compounds in any of the preceding claims nor are these compound numbers associated with a definitive structure.

102(e)/103(a)

Claims 12-22 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over 5,935,989.

Claims 12-22 are drawn to a pharmaceutical composition for treating a vision disorder, improving vision, treating memory impairment or enhancing memory performance in an animal, comprising an effective amount of an N-linked heterocyclic carboxylic acid or carboxylic acid isostere and a pharmaceutically acceptable carrier.

The pharmaceutical compositions of N-linked heterocyclic carboxylic acid or carboxylic acid of heterocyclic thioesters of Formula I of the instant claims have been set forth as pharmaceutical compositions in the claims and disclosure of '989. Hamilton et al. also teach aromatic substitutions such as unsubstituted or substituted mono, bi- or tricyclic, carbo- or heterocyclic rings with the compounds of the invention (col.3-col.9). The claims of the instant application differ only by the addition of further alkyl and aromatic groups, which constitute obvious substitutions in the Markush groups of the analogous compounds set forth in '989.

As the '989 patent teaches substitution of aromatic groups with the N-linked heterocyclic carboxylic acid or carboxylic acid of heterocyclic thioesters,it would have been obvious to one of skill in the art that further aromatic groups such as substituted (in 1-3 positions) furanyls, etc. could also serve as aromatic substituents.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Howard Owens whose telephone number is (703) 306-4538 . The examiner can normally be reached on Mon.-Fri. from 8:30 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the Primary Examiner signing this action, James O. Wilson can be reached on (703) 308-4624 . The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

JAMES O. WILSON
PRIMARY EXAMINER
GROUP 1600